



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Per Sonne HOLM, et al.

Examiner: WHITEMAN, Brian A.

Appln. No.: 10/029,574

Group Art Unit: 1635

Filed: December 20, 2001

Conf. No.: 4954

For: AGENTS FOR TREATING MALIGNANT DISEASES USING
PROTEIN YB-1

Attorney Docket No.: 3961.002

Customer Number: 00004288

RECEIVED

MAR 10 2004

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop: _____
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This election is responsive to the Office Action dated October 29, 2003, having an initial date for response of November 29, 2003, which is extended to March 1, 2004 (February 29, 2004 falling on a Sunday) by the Petition for Extension of Time for three (3) months, and fee of \$475 under 37 C.F.R. § 1.17(a) (small entity), submitted herewith. In said Office Action, the Examiner requires Applicant to elect for prosecution from either:

Group I - Claims 1-16 (drawn to an E1-deficient adenivirus comprising an YB-1 encoding DNA sequence and a method of using the adenovirus to treat tumors in a subject), or

Group II - Claims 17-20 (drawn to a method for E1-independent replication of a replication-defective adenovirus).

In response, Applicants elect Group I, **with traverse**.

Traversal is for the following reasons:

In issuing a Restriction Requirement, the Examiner **must satisfy two criteria for a proper restriction of the claims** of the application. First, he must show that the application claims independent or distinct inventions, as required by both § 121 and the USPTO rules. Second, the Examiner must show that examining all claims in a single application would constitute a serious burden upon the Examiner.

In the instant case, the Examiner fails to show that examining all claims inventions in a single application would constitute a serious burden, because, Applicant asserts, the Examiner fails to provide reasons or evidence on the record sufficient to substantiate either a separate classification, separate status in the art, or different field of search for the allegedly separate inventions.

Applicant asserts that the claims of Group I and Group II concern the same essential invention because both are directed to replication of an E1-deficient adenovirus in a cell comprising YB-1 in its nucleus for the treatment of tumors, the Groups differing only with respect to the comparatively minor aspect of the source of the YB-1. The Examiner's attention is respectfully drawn to paragraph [0013] of the specification, where the essence of the present invention is described:

[0013] The present inventors have surprisingly found that E1-deficient and more precisely E1A-deficient adenoviruses are able to replicate in cells which contain the factor YB-1 in the nucleus. Because of this relationship it is possible to use E1-deficient, and more particularly E1A-deficient adenovirus to infect YB-1 expressing tumor cells and thus allowing for replication and thus lysis of the tumor. Since the virus only replicates in cells in which YB-1 is located in the nucleus, only these cells are destroyed by the virus.

Therefore, all of the claims share a similar mode of operation, similar function, and similar effects (MPEP § 806.04, MPEP § 808.01). A search for the subject matter of Group I could be carried out concomitantly with the search for the subject matter of Groups II. It would not be unduly burdensome on the Examiner to examine both sets of claims simultaneously.

If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.

Accordingly, withdrawal of the Restriction Requirement is respectfully requested.

Respectfully submitted,

Christopher J. Kay
Reg. No. 44,820

Pendorf & Cutliff
5111 Memorial Highway
Tampa, Florida 33634-7356
(813) 886-6085

Dated: **March 1, 2004**

U.S. Application No. 10/029,574.
RESPONSE TO RESTRICTION REQUIREMENT

Attorney Docket No. 3961.002

CERTIFICATE OF MAILING AND AUTHORIZATION TO CHARGE

I hereby certify that the foregoing RESPONSE TO RESTRICTION REQUIREMENT for U.S. Application No. 10/029,574 filed December 20, 2001, were deposited in first class U.S. mail, postage prepaid, Mail Stop: _____, Commissioner for Patents P.O. Box 1450, Alexandria VA 22313-1450, on **March 1, 2004**.

The Commissioner is hereby authorized to charge any additional fees, which may be required at any time during the prosecution of this application, except for the issue fee, without specific authorization, or credit any overpayment, to Deposit Account No. 16-0877.

Christopher J. Kay